1638

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October 16, 2003

CERTIFICATE OF MAILING
37 C.F.R. 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:

October 16, 2003 — Date

Robert E. Hanson

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Re: SN 09/727,511 "INBRED CORN LINE LH246" - by Keith L. Arnold, et al.
Our Ref. HFSC:006US; Client Ref. 51632

Commissioner:

Enclosed for filing in the above-referenced patent application is:

1. A Response to Third Office Action Dated July 16, 2003; and

2. A return postcard to acknowledge receipt of these materials. Please date stamp and mail this postcard.

Should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to the enclosed materials, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/HFSC:006US.

Respectfully submitted,

Robert E. Hanson
Reg. No. 42,628

REH/vv
Enclosures

25347849.1 / 10208306

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Keith L. Arnold, et al.

Serial No. 09/727,511

Filed: December 4, 2000

Title: INBRED CORN LINE LH246

Group Art Unit: 1638

Examiner: David H. Kruse

Atty. Dkt. No.: HFSC:006US

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October 16, 2003
Date

Robert E. Hanson.

RESPONSE TO THIRD OFFICE ACTION DATED JULY 16, 2003

Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is submitted in response to the Third Office Action dated July 16, 2003, for which the three-month date for response is October 16, 2003. No fees are believed to be due in connection with the instant paper, however, should such fees be due consider this paragraph a request and authorization to withdraw the appropriate fee under 37 C.F.R. §§ 1.16 to 1.21 from *Fulbright & Jaworski, L.L.P.* Account No. 50-1212/HFSC:006US.

Reconsideration of the application is respectfully requested.

RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 1-11, 17-19 and 24 were pending at the time of the Third Office Action and are presented for reconsideration.

B. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Written Description

(1) Rejection of claim 6

The Action states that male sterile plants of variety LH246 in claim 6 have not been adequately described. In particular, it is stated that the specification only describes direct transformation of corn plant LH246 with a transgene. Applicants traverse.

Initially, it is noted that the claimed male sterile plant need not have itself been transformed with a gene conferring male sterility. For example, a parent LH246 plant may be transformed and crossed to another LH246 plant to yield the claimed plant; which would be a corn plant of LH246 comprising the introduced male sterility gene but not having itself been directly transformed. There is thus no basis to conclude that only direct transformation is described.

With regard to cytoplasmic male sterility, Applicants note that this is both well known in the art and described in the specification. For example, numerous different cytoplasmic male sterility genes and systems were patented in the U.S. prior to this application. For example, U.S. Patent Nos. 5,660,983 and 5,530,191 describe such cytoplasmic male sterility genes. U.S. patent No. 5,660,983 states that "Cytoplasmic male sterility (cms) is a ***well known phenomenon*** .... [that] has been ***most thoroughly studied and exploited in maize***." (emphasis added). Indeed, the use of cytoplasmic male sterility in corn was disclosed and claimed in U.S. Patent No. 2,753,663,

issued ***July 10, 1956***. Numerous other references also describe cytoplasmic male sterility. It has also been used commercially for years. It is therefore an understatement to say that cytoplasmic male sterility was well known in the art at the time the application was filed. This must be taken into account by the Office. Written description must be reviewed based on this knowledge in the art. *Wang Labs., Inc. v. Toshiba Corp.*, 993 F.2d 858, 863 (Fed. Cir. 1993). This is because the specification need not disclose what is well-known to those skilled in the art and preferably omits what is well-known and already available to the public. *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991).

The use of cytoplasmic male sterility is also described in the specification, for example, at page 6, lines 1-11, which read as follows:

> The laborious, and occasionally unreliable, detasseling process can be avoided by using cytoplasmic male-sterile (CMS) inbreds. Plants of a CMS inbred are male sterile as a result of factors resulting from the cytoplasmic, as opposed to the nuclear, genome. Thus, this characteristic is inherited exclusively through the female parent in corn plants, since only the female provides cytoplasm to the fertilized seed. CMS plants are fertilized with pollen from another inbred that is not male-sterile. Pollen from the second inbred may or may not contribute genes that make the hybrid plants male-fertile. Seed from detasseled fertile corn and CMS produced seed of the same hybrid can be blended to insure that adequate pollen loads are available for fertilization when the hybrid plants are grown.

Therefore, male sterile plants have been fully described. Removal of the rejection is thus respectfully requested.

(2) Rejection of claims 17 and 18

The Action rejects the claims as allegedly not describing F1 hybrid plants having LH246 as one parent. However, such plants have been fully described. Because corn plant LH246 is an inbred corn plant, all hybrid plants having LH246 as a parent will contain the same genetic contribution from LH246 and thus will be genetically distinct and identifiable from any other

corn plant on this basis. That is, because LH246 is an inbred corn plant, all hybrid corn plants derived therefrom will inherit half of their genetic material from corn plant LH246. All hybrid plant derived from LH246 will thus share this genetic contribution and be identifiable on this basis. The Federal Circuit has noted that such shared structural features possessed by members of a genus is important to the written description requirement. *The Regents of The University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997) (noting that a name alone does not satisfy the written description requirement where "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, *as one can do with a fully described genus, visualize or recognize the identity of the members of the genus*" (emphasis added)). Here, all of the members of the claimed genus of hybrids having LH246 as one parent share the structural feature of having the genetic complement of LH246. One of skill in the art could thus readily identify the members of the genus. The written description requirement has therefore been fully complied with.

The specification further describes specific examples of the claimed hybrid plants. In Tables 1-4, four F1 hybrids made using LH246 as one parent are described. This information, combined with the deposit of seed of LH246 and descriptions of the genetic and morphological characteristics of LH246 in the specification, is more than adequate to provide a description of hybrid plants and seeds derived from corn plant LH246 in compliance with the written description requirement. While the claims are directed to a genus of plants, these hybrids constitute a representative set of species describing the genus based on the shared structural characteristics of the members of the genus.

The foregoing examples constitute a representative set of species supporting a description of the genus of transformed LH246 plants. To conclude otherwise would limit Applicants to that subject matter described *ipsis verbis* in the specification. This position is expressly contradictory to Federal Circuit precedent. *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) (stating that the written description requirement does not require an applicant to "describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (citations omitted)). While Applicants have not described every possible single species of transgenes introduced into LH246, this is not required to provide a written description of a genus. *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). As such, Applicants have fully complied with the written description and removal of the rejection under 35 U.S.C. §112, first paragraph, is thus respectfully requested.

C. Rejection of Claims Under 35 U.S.C. §112, First Paragraph – Enablement

(1) Rejection of claim 6

The Action rejects claim 6 as not enabling production of male sterile corn plants. In particular, the Action alleges that the specification does not adequately describe the corn variety LH246 comprising a comprising a gene conferring male sterility. Applicants respectfully traverse.

It is first noted that all that is required to satisfy the enablement requirement of 35 U.S.C. §112, first paragraph, is that Applicants teach one reasonably skilled in the art how to make and use the claimed invention without undue experimentation. *In re Wands*, 858 F.2d 731, 737, 8

USPQ2d 1400, 1404 (Fed. Cir. 1988). The specification has done this and thus fully meets the requirement.

The specification provides corn line LH246, which will be deposited upon the indication of otherwise allowable subject matter. The specification also describes numerous plant transformation techniques that are known in the art at pages at pages 29-31, including: *Agrobacterium*-mediated transformation; microprojectile-mediated transformation; sonication of target cells; liposome or spheroplast fusion; electroporation of protoplasts and whole cells and tissues; and direct uptake of DNA into protoplasts using $CaCl_2$ precipitation, polyvinyl alcohol or poly-L-omithine. No allegation has been made that any of these techniques are not enabling for transformation of maize.

The specification further describes numerous coding and regulatory sequences for transformation into corn plant LH246 using the transformation techniques described including examples of genes conferring male sterility (see genes plant disease resistance genes, *Bacillus thuringiensis* protein genes. For example, page 6, lines 1-1 of the specification describe use of cytoplasmic genes conferring male sterility as follows:

> The laborious, and occasionally unreliable, detasseling process can be avoided by using cytoplasmic male-sterile (CMS) inbreds. Plants of a CMS inbred are male sterile as a result of factors resulting from the cytoplasmic, as opposed to the nuclear, genome. Thus, this characteristic is inherited exclusively through the female parent in corn plants, since only the female provides cytoplasm to the fertilized seed. CMS plants are fertilized with pollen from another inbred that is not male-sterile. Pollen from the second inbred may or may not contribute genes that make the hybrid plants male-fertile. Seed from detasseled fertile corn and CMS produced seed of the same hybrid can be blended to insure that adequate pollen loads are available for fertilization when the hybrid plants are grown.

At page 6, lines 6-12, other genes for conferring male sterility are described as follows:

> There are several methods of conferring genetic male sterility available, such as multiple mutant genes at separate locations within the genome that confer male

> sterility, as disclosed in U. S. Patent Nos. 4,654,465 and 4,727,219 to Brar et al. and chromosomal translocations as described by Patterson in U. S. Patent Nos. 3,861,709 and 3,710,511. These and all patents referred to are incorporated by reference. In addition to these methods, Albertsen et al., U. S. Patent No. 5,432,068 have developed a system of nuclear male sterility which includes: identifying a gene which is critical to male fertility, silencing this native gene which is critical to male fertility; removing the native promoter from the essential male fertility gene and replacing it with an inducible promoter; inserting this genetically engineered gene back into the plant; and thus creating a plant that is male sterile because the inducible promoter is not "on" resulting in the male fertility gene not being transcribed. Fertility is restored by inducing, or turning "on", the promoter, which in turn allows the gene that confers male fertility to be transcribed.

Still further, page 6, line 27 to page 7, line 4 of the specification describe use of antisense technology to confer male sterility as follows:

> There are many other methods of conferring genetic male sterility in the art, each with its own benefits and drawbacks. These methods use a variety of approaches such as delivering into the plant a gene encoding a cytotoxic substance associated with a male tissue specific promoter or an anti-sense system in which a gene critical to fertility is identified and an antisense to that gene is inserted in the plant (see, Fabinjanski, et al. EPO 89/3010153.8 publication no. 329, 308 and PCT application PCT/CA90/00037 published as WO 90/08828).

As can be seen, the specification describes male sterility in great detail. This is underscored by the fact that male sterility in maize is well known in the art and has been used for many years, as described above. Combined with the detailed breeding methodology and genetic transformation techniques described in the specification, it is clear that one of skill in the art could readily prepare a male sterile plant from LH246. The claimed male sterile plant need not have itself been transformed with a gene conferring male sterility. For example, a parent LH246 could have been transformed and crossed to another LH246 plant to produce the claimed plant, which would comprise the male sterility gene but would not have itself been directly transformed. In this manner, Applicants enable a plant of LH246 comprising a male sterility gene regardless of the means by which it is created.

In an attempt to support the rejection, the Action cites several references alleged to show the difficulty of making male sterile or single locus converted plants. However, no basis has been given to show that these references have any relevance to *corn* plants. Hunsperger deals with petunias; Kraft with sugar beets and Eshed with Tomatoes. No allegation has been made that the references refer to corn plants. The relevance of the references to the claimed invention has therefore not been established as is specifically required to establish a *prima facie* case of non-enablement.

It is finally noted that the Action provides no basis for doubting the sufficiency of the teaching in Applicants' specification and thus the enablement of Applicants' claims. A mere allegation that Applicants have not met the enablement requirement of 35 U.S.C. §112, first paragraph, will not support a rejection, "[o]therwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure." *In re Marzocchi*, 169 U.S.P.Q. at 370. Absent such a basis, the rejection must fail.

In view of the foregoing Applicants respectfully request the removal of the rejection

(2) Rejection of claims 17 and 18

The Action rejects claims 17 and 18 as not describing hybrid corn plants, one of the parents of which is LH246. Initially, Applicants note that this is an enablement rejection and thus the relevant issue is whether Applicants have taught one of skill in the art how to make and use the claimed invention. As set forth below, Applicants have fully done so.

Applicants note that all that is required to produce hybrid plants having LH246 as one parent is to cross a plant of LH246 to any different second plant. The comments about linkage disequilibrium are inapposite. A plant having LH246 is made any time LH246 is crossed to another corn plant. Therefore, the only way that LH246 could be considered to not be enabled

for corn plants having LH246 as one parent is to assume that LH246 is not fertile. However, LH246 is fertile. This is illustrated in Tables 1-4 of the specification, which describe the production of four different hybrids with LH246 as one parent. The working examples therefore demonstrate full enablement of hybrid plants.

In view of the foregoing, removal of the rejection is respectfully requested.

(3) Rejection of claims 1-11, 17-19 and 24

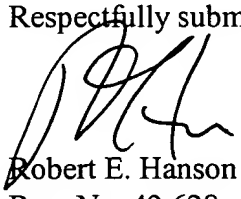
The Action maintains the rejection of the claims based on a lack of a seed deposit. In response, Applicants note that a deposit of 2500 seeds of the claimed variety will be made with the ATCC in compliance with the terms of the Budapest treaty upon the allowance of the case. Removal of the rejection is thus respectfully requested.

D. Conclusion

This is submitted to be a complete response to the referenced Office Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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